Protocol

for an Oral Anticoagulation Clinic

Please note that this protocol outlines minimum requirements for an Oral Anticoagulation Clinic's management of Vitamin K antagonists

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Aim

The service will offer equitable, standardised and clinically effective anticoagulation management for patients receiving anticoagulation therapy.

Objectives

- To receive, manage and ensure appropriate referral of patients who require anticoagulation therapy either registered or non-registered in the practice, excluding novel oral anticoagulation (NOAC) therapy
- To ensure all patients have a treatment plan reviewed on a regular basis (annually)
- To identify patients with specific needs, i.e. poor compliance, unstable INR control or frequent non-attenders for review by designated clinician
- To educate new and review patients in understanding their treatment, in terms of their condition requiring anticoagulation, target range for INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions
- To advise on anticoagulant therapy regimen prior to surgery or dental care (BCSH guidelines)
- To provide optimum care in accordance with the NPSA guidelines in terms of:
- INR control, e.g. 60-70% of individual patients' INR tests in range at any given time
- Identifying and managing clinical events related to anticoagulation therapy
- Considering the impact of patient choice (patient satisfaction questionnaire annually e.g. accessibility, waiting time, and continuity of care
- To ensure safe and accurate recording of all clinical data using the relevant CDSS system with relevant back up documentation in case of electrical breakdown
- To evaluate the quality of care given through regular audit process, effecting change when required to achieve planned goals
- To ensure relevant, complete and accurate documentation of the clinic process
- To undertake an annual review and update of the protocol

Exceptions (primary care)

- Patients under 16 years of age
- Patients with complex pathologies following discussion with specialist e.g. atypical systemic emboli, anything not listed under routine indications for anticoagulation

Indications for warfarin use and target INR

The indications and targets are taken from British Society of Haematology guidelines Baglin T, Keeling D, Watson H. Guidelines on oral anticoagulation (warfarin): third edition – 2005 update BJ Haem 2005; **132**: 277-285

Other targets will be acceptable for named patients after discussion with designated clinician.

Target INR 2.5

Pulmonary embolus

Proximal DVT

Calf vein thrombosis

Non-rheumatic atrial fibrillation

Atrial fibrillation other causes

Mural thrombus

Cardiomyopathy

Symptomatic inherited thrombophilia

Antiphospholipid syndrome

Bioprosthetic valve if anticoagulated

Arterial grafts if anticoagulated

Mechanical prosthetic aortic valve (or 3.0)

Cardioversion (or 3.0)

Target INR 3.5

Recurrence of venous thromboembolism whilst on warfarin therapy

Mechanical prosthetic valve (or 3.0)

Not indicated

Ischaemic stroke without AF

Retinal vein occulsion

Peripheral arterial thrombosis and grafts

Coronary artery thrombosis

Coronary artery graft thrombosis

Coronary angioplasty & stents

Risk management

Assess risk to both patient and health care professional

Implement risk reduction strategies incorporated into the clinic management

1. Patients lost to follow-up
2. Inadequate or lost referrals
3. Inadequate documentation
4. Inadequate updated staff training
5. Point of care failure
6. Insufficient clinic time/space for appointments education and discussion
7. Inappropriate dose and monitoring interpretation
8. System network crash
9. Health and safety blood spillage, cross contamination

Implementation of risk reduction strategies must be done with reference to relevant clinical governance authorities where appropriate.

Management of clinic

- Inform hospital/primary care clinics currently managing patient of new clinic
- Train a nurse in anticoagulation management to manage the clinic with support from a designated clinician
- Estimate the INR using a Point of Care (POC) device.
- Interpret the INR result with the assistance of computerised decision support software (CDSS)
- Perform internal quality control at the start of each clinic and after every 20 INR tests using material supplied by the manufacturer.
- Perform external quality control every three months using samples from an external quality assessment scheme e.g. NEQAS
- Adhere to health and safety procedures recommended by laboratory staff to protect both the patient and clinical staff at all times
- There needs to be a qualified clinician in place for the day to day clinical management of the Anticoagulation clinic.
- A doctor will be on site whenever the anticoagulation service is provided
- These clinicians are together responsible for initial review and producing treatment plan plus annual review of patients and update of the clinical protocol to support the anticoagulation service.
- The clinicians will be responsible for the regular review of audit information in respect of this service, making recommendations for any improved working as appropriate.

Suggestions for manual recall periods in case of CDSS breakdown

One high INR greater than or equal to 5 – recall 7-14 days
One high INR greater than or equal to 6 – recall within 5 days

One low INR 1 unit below target – recall 7-14 days
One therapeutic INR – recall 2-4 weeks
Two therapeutic INRs – recall 6 weeks
Three therapeutic INRs – recall 8 weeks
Four therapeutic INRs – recall 10 weeks
Five therapeutic INRs – recall 12 weeks

Identify key personnel

Establish effective routes of communication between some of the following:

- Haematologist / Anticoagulant nurse specialist nurse (named)
- Lead general practitioner (named)
- Lead Practice nurse (named)
- Laboratory contact (named)
- Anticoagulant clinic contact (named)
- Pharmacist
- ICT personnel
- Administrator

Training

The clinic will be managed by trained staff – see Warfarin Oral Anticoagulation Service Specification, **Training and Accreditation**

Personnel responsible for the clinic are aware of professional accountability and undertake the clinic management only if they feel competent to do so.

Accredited courses are available. Personnel managing the clinic will also be aware of continued professional development and attend regular updates on anticoagulation management.

Training should include:

- An introduction to oral anticoagulation therapy, an understanding of the test to be performed, the INR and how it is derived
- An understanding of the specific POC device for deriving INR, setting up and using the device
- The target INR, how it relates to diagnosis, action if results outside limits
- Recording of results and quality assurance materials
- Health and safety – disposal of sharps, Control of Substances Hazardous to Health (COSHH) regulations

Standard operating procedures will be needed when using POC devises identification and referral of patients

The practice computer database will identify most patients. In addition patients can be identified from anticoagulation therapy prescriptions. Regular computer searches (every 3 months) will check for new patients to the practice receiving anticoagulation.

Referrals to the service should be made using the appropriate referral form (see appendix B) of the Warfarin Oral Anticoagulation Service Specification.

Telephone referrals cannot be accepted unless under exceptional circumstances.

All patients will remain the responsibility of the referring centre until the patient is seen in the clinic.

Clinic Procedure for patients receiving warfarin

- Prepare POC device and complete internal quality control procedure. Document control result, batch numbers of strips and controls, user ID
- Counsel patient regarding clinic process and check for:
  - Bleeding or thrombotic incidences
  - Tablet compliance and change of medication
  - Lifestyle changes e.g. alcohol binges
- Perform blood test using capillary blood. Venous samples can be taken at patient request or for capillary results greater than POC upper limits.
- Perform INR test using POC device and enter results into the decision support software.
- Follow suggestions given by computer for dosing and recall dates unless clinically inappropriate e.g. patient known to be non-compliant with therapy.
- Complete patient record card and give to patient with verbal instruction regarding dosage and recall.
- Record INR, warfarin dosage and recall date in patient's notes and practice computer.

Annual review

- Assess condition requiring warfarin – risk / benefit – annual specialist or clinician follow up, check recommended period of time on warfarin
- Assess whether warfarin therapy is still appropriate e.g. dementia, multiple ADRs
- Assess patient satisfaction using a simple questionnaire (See Appendix I of service specification for example questionnaire)

Haemorrhagic risk assessment (Beyth)

Score 1 each that apply

Age >65

History of stroke

History of gastrointestinal bleed

One or more of:

- Recent MI
- Diabetes

Score 0 – low bleeding risk 2-3% in the first year
Score 1-2 - Intermediate risk of bleeding in the first year
Score 3-4 – High risk of bleeding in the first year

New patients

- Review treatment plans of all new patients, ensure all patient details are entered and correct in both yellow record book and referral letter and patient is given information sheets and record book.
- Ensure that patient has correct target range, duration of treatment for condition requiring warfarin. If not, referring clinician should be consulted.
- Educate about warfarin treatment, target range, effects of over and under anticoagulation, diet, lifestyle and drug interactions.
- Explain the clinic system with regard to blood testing, dosing and next test date.

Clinical guidelines for initiation of warfarin

Patients having warfarin initiated for AF in the community should have a baseline INR performed. Warfarin should only be initiated in the baseline INR is less than 1.3. Any patient with a baseline INR of 1.3 or above should be screened for underlying conditions. Check FBC, LFTs, clotting screen.

The initiation dose for patients commencing warfarin for AF in the community should be 1-3mg daily. Check INR after one week and then weekly until INR within therapeutic range and then dose according to result using CDSS.

Clinical guidelines for over anticoagulation

If INR greater than 5.0 on POC

Assess for clinical signs of bleeding and consider administration of Vitamin K.(In practice clinic, or refer to hospital A/E)

If no bleeding, follow CDSS guidelines for suspension of treatment.

If bleeding, refer to GP/hospital

If INR greater than 8.0 refer to hospital for vitamin K (iv preparation given orally or IV – see pg 8)

Check INR the next day

BSH guidelines for INR greater than 5.0

3.0 < & <6.0 (target 2.5)
Reduce or stop warfarin, restart when INR <5.0

4.0 < & <6.0 (target 3.5)
Reduce or stop warfarin, restart when INR <5.0

6.0 < & <8.0 – No bleeding or minor bleed
Stop warfarin, restart when INR <5.0

INR >8.0 – No bleeding or minor bleeding
Admit to hospital for Vit K 0.5mg **Or** GP for IV Vit K 0.5 mg **or** oral Vit K 0.5 - 2.5 mg for partial reversal

Major bleeding
Stop warfarin; admit to hospital for urgent reversal (prothrombin complex concentrate/FPP) and IV Vit K 5-10mg.

Definition of serious and non-serious adverse events

Serious adverse event

- Bleeding: If admitted to hospital or if surgery was required to stop bleeding and if bleeding led to reduction of Hb of 2 g/dL or more and/or requiring blood transfusion[1]
- Thrombotic: Transient Ischaemic Attack (with observed neurological deficit) or Stroke, recurrent Deep Vein Thrombosis and Pulmonary Embolism, Systemic Embolism.

Non serious

- All cases of bleeding with no associated costs or medical consequences, e.g. bruising, small epistaxis, microscopic haematuria.

[1] Palareti G, Leali N, Coccheri S, Poggi M, Manotti C, D'Angelo A et al. Bleeding complications of oral anticoagulant treatment: an inception-cohort, prospective collaborative study (ISCOAT). Lancet 1996; 348: 423 - 428

Advice to patient having dental treatment

Patients are advised to continue with warfarin therapy when attending for dental treatment. However, they will need to check their INR the day before the appointment to ensure the INR is below 4.0.

Pre-operative management of warfarin

If major surgery – stop warfarin 4 days before surgery, heparin introduced pre-op in hospital

If minor surgery – reduce INR to approximately 2.0 on day of surgery (Liaise with hospital to discuss warfarin dosage on discharge)

Guidelines for discontinuing warfarin

To discontinue warfarin at treatment completion, obtain written confirmation from clinician that commenced warfarin therapy. The end date of treatment should be clarified on original referral form.

Administrative Tasks

Perform a weekly computer search for non-attendees to warfarin clinic

Contact non-attendees to the clinic with a letter/telephone call and a new appointment

Produce and send patient satisfaction questionnaire

Undertake referrals to other clinics as necessary

Undertake stock control as necessary

Arrange protocol and clinical meetings as necessary

Ensure training of key personnel is up to date

Forward anticoagulant therapy cards of moved away patients to designated GP or re-refer to hospital anticoagulant clinic if necessary.

Perform a backup of software at the end of each clinic

Audit (Safety indicators)

To be performed at least annually, reviewed and changes made where needed.

- INR results in terms of percentage time in range
- IQC and EQA results
- Adverse major events (e.g. any bleed requiring hospital admission & any thrombotic event).
- Patient satisfaction
- Numbers attending the clinics
- Attendance rate and waiting time
- Patient complaints
- DNA rate

(See NPSA report for further parameters)